

EXHIBIT A

**UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

***City of Roanoke Virginia v.
Mallinckrodt PLC, et al.***
Case No. 1:19-OP-45696

MDL No. 2804

Case No. 1:17-MD-2804-DAP

Judge Dan Aaron Polster

**DECLARATION OF WILLIAM T. CAHILL IN SUPPORT OF
THE EXPRESS SCRIPTS DEFENDANTS OPPOSITION
TO PLAINTIFF’S MOTION TO REMAND**

I, William T. Cahill, declare as follows:

1. My name is William T. Cahill. I am over the age of 18 and competent to provide this declaration in support of the Opposition to Plaintiff's Motion to Remand filed on behalf of Express Scripts, Inc., Express Scripts Holding Company, Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc. (collectively, "Express Scripts"). I refer to the mail pharmacy entities, Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc., here as "ESI Mail Pharmacy."

2. I am employed by Express Spirits, Inc. and serve as Vice President of Account Management at Express Scripts, Inc.

3. Express Scripts, Inc. contracts with the U.S. Department of Defense (“DOD”) through the Express Scripts Military Health Statement of Work (“SOW”). In my capacity as Vice President of Account Management, I was responsible for managing the SOW from 2018-2021.

My discussion below of the SOW is of the SOW that was in effect in March 2019 (and continued to be in effect during the time period that I was responsible for managing the SOW).

4. The DOD manages TRICARE, which is the military's healthcare program for uniformed service members and their families. The DOD provides pharmaceuticals to beneficiaries through the TRICARE pharmacy benefits program. Program beneficiaries receive drugs through four "points of service," one of which is the TRICARE Mail Order Pharmacy ("TMOP").

5. In 2018 and 2019, the DOD was Express Scripts second-largest client. As reported on Express Scripts' quarterly earnings, as of September 30, 2018, the DOD accounted for 12% of Express Scripts' revenue. As of September 30, 2019, after the combination of Express Scripts and Cigna Corporation and as reported in Cigna's quarterly earnings, the DOD accounted for 8% of the combined company's Health Services segment's revenues.

6. Additionally, according to data and information made available to me, from 2014-2019, the number of TRICARE members with pharmacy claims in the State of Virginia, which includes TRICARE members with prescription claims in the City of Roanoke, ranged from approximately 15.5% in 2014 to approximately 25.5% in 2019, of the total number of Express Scripts members with prescription claims.

7. Under the DOD contract, Express Scripts, Inc. and its affiliates, including Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc., provide online claims adjudication, home delivery services, specialty pharmacy clinical services, claims processing and contact center support and other services critical to managing pharmacy trends.

8. The DOD contract requires Express Scripts to provide services to members of the DOD health care program, TRICARE, across the country, including in the City of Roanoke,

Virginia. Express Scripts, Inc. provides pharmacy benefit management services, and ESI Mail Pharmacy administers the TRICARE Mail Order Pharmacy (“TMOP”) under the detailed requirements of the contract.

9. The DOD contract incorporates the TRICARE program statutory and regulatory requirements with supplemental TRICARE manuals. These together with the SOW provide detailed instructions on every aspect of how Express Scripts, Inc. administers the PBM services for the TRICARE program and how ESI Mail Pharmacy administers the TMOP. (SOW C.5.)

10. As one example, the contract requires the exclusive use of the DOD formulary created by the DOD’s own Pharmacy & Therapeutics (“P&T”) Committee.

11. The SOW also has several detailed requirements that Express Scripts, Inc. fulfills to provide Pharmacy Benefit Management Services (SOW C.6):

- a. Specific line items requiring “General Claims Processing” including claims adjudication consisting of eligibility check, application of the correct copayment, identification of other health insurance, benefit design edits, prospective drug utilization review and application of catastrophic cap updates, page 4;
- b. Specific line items requiring accepting and processing “all claims for pharmaceutical agents and diabetic supplies covered under the TRICARE pharmacy benefit, and purchased from a licensed pharmacy” page 7;
- c. The provision that “[r]etail claims for covered drugs will be limited by requirements under 10 U.S.C. § 1074g, 32 CFR 199.21, and other applicable regulations,” *Id.* The cited statutory provision governs the “Pharmacy Benefits Program” of the TRICARE statute. The cited regulation imposes detailed requirements and is attached here as Exhibit A.

12. Under the SOW, the Express Scripts entities implement restrictions on prescriptions imposed by TRICARE: Express Scripts shall “manage the Prescription Restriction Program” and “coordinate efforts to identify potential candidates” for “restrictions based upon the number of controlled medications filled, the number of physicians prescribing controlled medications and the number of pharmacies that fill these prescriptions,” page 28. A Military Treatment Facility or Managed Care Support Contractor must determine if a restriction is appropriate. If it is, Express Scripts, Inc. either restricts the beneficiary “so all medications, or specific medications must be prescribed by a specific provider(s) and / or filled at a specific pharmacy(ies)[.]” or “[r]equire[s] the beneficiary to pay 100% of the cost of the restricted medications” *Id.* Under the SOW, Express Scripts, Inc. sends a notification letter to the beneficiary. *Id.*

13. The SOW dictates how Express Scripts, Inc. must provide the PBM services such as, for example:

- a. Beneficiary identifier to be used in processing claims (section C.6.1.5);
- b. Claims processing 24 hours a day, 7 days a week (section C.6.1.3);
- c. Use of applications provided in the incorporated TRICARE Operations Manual (“TOM”) (section C.6.1.4);
- d. Adherence to the DOD Uniform Formulary including monitoring and implementing uniform formulary changes (section C.8.1.3); and
- e. Mailing notices to newly-eligible beneficiaries on a quarterly basis with minimum requirements for the mailings (section C.10.4.1).

14. Express Scripts, Inc. is not itself a mail order pharmacy. Rather, Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc. fulfill the SOW requirements to operate the

TMOP under a shared service agreement. Express Scripts Pharmacy, Inc. processes prescription orders. ESI Mail Pharmacy Service, Inc. is a licensed pharmacy that processes and dispenses prescriptions.

15. The DOD, through the Defense Logistics Agency, is aware of and has approved the use of the ESI Mail Pharmacy for delivery of pharmaceuticals used in the TMOP. The Defense Logistics Agency is responsible for contracting with the National Prime Vendor (“NPV”) who purchases and distributes replenishable pharmaceutical agents as required by the DOD.¹

16. The SOW requires Express Scripts to coordinate with the Defense Logistics Agency and the DOD’s NPV of pharmaceuticals to deliver and replenish pharmaceuticals that ESI Mail Pharmacy dispenses through their operation of the TMOP (section G.7.1: “The Government will bear the cost of prescriptions dispensed at the MOP under this contract by providing drug replenishment through Defense Supply Center, Philadelphia (DSCP) and the National Prime Vendor (NPV) per section C.3.”).

17. As part of this replenishment process, when ESI Mail Pharmacy adds a location for delivery of pharmaceuticals for the TMOP, that site must be approved by the government and added to the list of site specific identifiers that the government uses when it orders pharmaceuticals that the NPV delivers to an ESI Mail Pharmacy location.

18. The government incorporates prescription fulfillment centers operated by ESI Mail Pharmacy into the NPV contract, which allows the ESI Mail Pharmacy facilities to receive the pharmaceutical products from the NPV. Therefore, the government is not only aware that the ESI

¹ See, e.g., <https://www.dla.mil/Portals/104/Documents/Headquarters/DLA%20At%20A%20Glance/DLAFactSheetJanuary2020.pdf>.

Mail Pharmacy operates the TMOP, but it also reviews and approves of the delivery of pharmaceutical products to the ESI Mail Pharmacy for use in the administration of the TMOP.

19. As part of its obligations under the SOW (for example, Section C.16), Express Scripts also notifies the government when it adds ESI Mail Pharmacy employees to perform work under the DOD contract, and provides reports to the government about those employees as required. Those employees are also trained on the DOD contract, as required by the SOW.

20. The SOW has several additional detailed requirements that are fulfilled by ESI Mail Pharmacy, including:

- a. Specific line items requiring “Mail Order Pharmacy, Prescription Fill, TRICARE Only-Eligible” with an estimated quantity of 4,930,000 on page 5; 5,500,000 on page 14; 6,000,000 on page 23; 6,100,000 on page 32; 6,500,000 on page 42; 6,800,000 on page 51; 7,200,000 on page 61;
- b. Specific line items requiring “Mail Order Pharmacy, Prescription Fill, Medicare Dual-Eligible” with an estimated quantity of 22,100,000 on page 5; 24,150,000 on page 14; 25,000,000 on page 23; 24,100,000 on page 33; 25,400,000 on page 42; 26,750,000 on page 52; 28,000,000 on page 61;
- c. The provision of mail order pharmacy benefits to all eligible TRICARE beneficiaries (sections C.1.3, C.1.4);
- d. The operation of the TRICARE Home Delivery/Mail Order Pharmacy (TMOP) (section C.1.5); and
- e. “Provide comprehensive mail order and specialty pharmacy fulfillment services that are efficient, accurate, cost-effective, and maximize patient safety” (section C.2).

21. The SOW dictates how the ESI Mail Pharmacy must operate the TMOP including:
 - a. Pricing and replenishment practices (sections C.4.4, C7.1.11);
 - b. Verification of eligibility (section C.6.1.4);
 - c. Prospective Drug Utilization Review (section C.6.1.10);
 - d. Receipt and verification of prescriptions (section C.7.1.1);
 - e. Prescription processing, including shipment specifications, and accuracy in dispensing requirements (sections C.7.1.2, C.7.1.12, C.7.3, C.7.4);
 - f. Reporting of mail order volumes, processing times, claims review and accuracy to the DOD (sections C.7.1.3; C.7.1.14, C.7.6, C.11.5);
 - g. Timing and documentation of clarification or intervention (section C.7.1.4);
 - h. Contact with TRICARE beneficiaries (sections C.7.1.5, C.7.1.6, C.7.1.8, C.7.1.9);
 - i. Adherence to the Government's mandatory generic policy (section C.7.1.7);
 - j. Refills (sections C.7.1.10, C.7.14.1);
 - k. TMOP registration (section C.7.2.1);
 - l. Payment methods and collection of copayments (sections C.7.2.2, C.8.2);
 - m. Conversions of retail to mail order prescriptions (section C.7.7);
 - n. Conversions of prescriptions from military treatment facilities to mail order prescriptions (section C.7.8);
 - o. TMOP for TRICARE beneficiaries who are deployed or at U.S. Embassies or "in-theater locations" (section C.7.10); and
 - p. Provision of inventory of pharmaceutical agents and supplies for dispensing to TRICARE beneficiaries (section C.7.11), among other requirements.

22. By the express terms of the SOW, the mail order pharmacy administration, including for prescription opioids, is governed by multiple federal regulations and manuals and overseen by a federal contracting officer.

23. The Department of Defense has a contracting officer (“CO”) who is responsible for management of the SOW. The SOW identifies a specific person as the CO, and the contract is amended whenever the identity of the CO changes.

24. Representatives of Express Scripts, Inc. are the primary client contact and regularly meet with representatives of the Department of Defense to discuss performance of the DOD contract, including mail order pharmacy administration. Express Scripts, Inc. representatives brief the CO weekly and have a formal program review three times a year. There is also daily interaction between Express Scripts, Inc. representatives and the CO regarding contract administration and execution. Express Scripts, Inc. communicates guidance and instruction from the CO or other Government representatives to the ESI Mail Pharmacy as needed to execute the SOW.

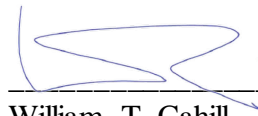
25. When DOD wishes to change or modify the SOW with respect to operation of the TMOP, it issues a written Change Order or Contract Modification to Express Scripts, Inc., which communicates the change or modification to the ESI Mail Pharmacy to execute.

26. Representatives of the ESI Mail Pharmacy also interact with DOD representatives. For example, DOD representatives have visited the ESI Mail Pharmacy sites to review the operations. During those visits, ESI Mail Pharmacy employees give DOD representatives a tour of the facilities, as those employees operating the pharmacies are the only employees allowed to escort visitors to the pharmacy. During at least one visit, ESI Mail Pharmacy employees showed DOD representatives specialized bottle tops approved for use for TRICARE prescriptions.

27. DOD representatives also interact directly with ESI Mail Pharmacy employees during some audits that are performed under the contract. The SOW provides that any discrepancies “shall be subject to Contractor desktop audits and, if necessary, on-site audits at the direction of the Government.” (SOW, at 37.) With respect to pharmacies, “[t]he Government reserves the right to direct audits of retail or mail pharmacies. In addition to any Contractor initiated on-site audits for which TRICARE is the primary focus of the audit, the Government may direct up to 50 on-site audits per option year.” *Id.*

Pursuant to 28 U.S.C. § 1764, I declare under penalty of perjury that the foregoing is true and correct.

Dated this 29th day of September, 2022.



William T. Cahill